

# Exhibit A



**Sarah P. Kelly**  
Direct Line: 617-439-2461  
Fax: 617-310-9461  
E-mail: skelly@nutter.com

March 9, 2015  
114026-1

**Via U.S. Mail and Electronic Mail**

Kenneth B. Walton, Esq.  
Kristen R. Ragosta, Esq.  
Donovan Hatem, LLP  
53 State Street, 8<sup>th</sup> Floor  
Boston, MA 02109

Re: *In re: New England Compounding Pharmacy, Inc., Products Liability Litigation*  
Case No. 1:13-md-02419-RWZ

Dear Mr. Walton and Ms. Ragosta:

Regarding the above-referenced case, enclosed please find Saint Thomas Entities' First Set of Interrogatories, Requests for Production, and Requests for Admission to ARL Biopharma, Inc.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink that reads "Sarah P. Kelly". Below the signature, the name "Sarah P. Kelly" is printed in a smaller, standard font.

SPK/jme  
Enclosure

cc: All Counsel on Certificate of Service (*via email*)

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING ) PHARMACY, INC. PRODUCTS LIABILITY ) LITIGATION ) )	)
THIS DOCUMENT RELATES TO: ) )	MDL No. 2419 Dkt. No 1:13-md-2419 (RWZ)
All Suits Against the Saint Thomas Entities ) )	)
)	)
)	)

**SAINT THOMAS ENTITIES' FIRST SET OF INTERROGATORIES, REQUESTS FOR  
PRODUCTION, AND REQUESTS FOR ADMISSION TO ARL BIOPHARMA, INC.**

Come the Defendants, Saint Thomas West Hospital f/k/a St. Thomas Hospital; Saint Thomas Health; and Saint Thomas Network (collectively the "Saint Thomas Entities"), and submit the following Interrogatories, Requests for Production, and Requests for Admission to ARL BioPharma, Inc. pursuant to Rules 26, 33, 34 and 36 of the Federal Rules of Civil Procedure and Local Rules 33.1, 34.1 and 36.1.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within 30 days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your responses with respect to any request directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response,

though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

Regarding the following Requests for Admission, Rule 36 of the Federal Rules of Civil Procedure sets forth the following instructions:

- a. The grounds for objecting to a request must be stated.
- b. A denial must fairly respond to the substance of the requested admission.
- c. In the event a portion of the requested admission is true, the party must specify so much of the requested admission that is true, and then qualify or deny the remainder.
- d. The answering party may assert lack of knowledge or information as a reason for failing to admit or deny only if the party states that it has made reasonable inquiry and that the information it knows or can readily obtain is insufficient to enable it to admit or deny.
- e. A party must not object solely on the ground that the request presents a genuine issue for trial.

### **INSTRUCTIONS AND DEFINITIONS**

#### **I. INSTRUCTIONS**

- A. If you object to any of the following requests, please respond to as much of the request as to which you have no objection.
- B. Your response must include your answers to the Interrogatories and may include objections and assertions of privilege as required under these rules.
- C. If you withhold information pursuant to a claim of privilege, please state:
  - 1) that information or material responsive to the request has been withheld;
  - 2) the request to which the withheld material or information relates; and
  - 3) the privilege or privileges asserted.
- D. You are under a duty to supplement the following responses if you learn that they were incomplete or incorrect when made or, although complete and correct when made, are no longer complete and correct:

- 1) to the extent that the written discovery seeks the identification of persons with knowledge of relevant facts, trial witnesses or expert witnesses; and
  - 2) to the extent that the written discovery seeks other information, unless additional or corrective information has been made known in writing, on the record at a deposition, or through other discovery responses.
- E. An amended or supplemental response to these requests must be made reasonably promptly after you discover the necessity for such response, but in no event less than 120 days prior to trial.
- F. In the event any question cannot be fully answered after the exercise of reasonable diligence, please furnish as complete an answer as you can and explain in detail the reasons why you cannot give a full answer.
- G. Unless otherwise noted, the timeframe for these discovery requests is on or before December 31, 2012.

## II. DEFINITIONS

- A. As used herein, “ARL,” “you,” and “your” refer to ARL BioPharma, Inc. d/b/a Analytical Research Laboratories, an Oklahoma corporation with a principal place of business located at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- B. As used herein, the term “Lawsuit” refers to all lawsuits involved in *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 2419, Dkt. No. 1:13-md-2419, pending in the United States District Court for the District of Massachusetts.
- C. As used herein, “Plaintiff” and “Plaintiffs” refer to the Plaintiffs in this Lawsuit who have pending and active cases, as well as their agents, heirs, personal representatives, and assigns, and each person acting or purporting to act on his/her/their behalf.
- D. As used herein, “NECC” refers to New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, with its principal place of business located in Framingham, Massachusetts, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.
- E. As used herein, “Ameridose” refers to Ameridose, LLC, a Massachusetts limited liability company with its principal offices located at 205 Flanders Road, Westborough, Massachusetts, and each of its present and former owners, managers, agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his/her/their behalf.

- F. As used herein, the term “NECC facility” refers to the facility located on Waverly Street, Framingham, MA 01702, where compounding of the pharmaceuticals at issue in this Lawsuit occurred.
- G. As used herein, the term “MPA” means methylprednisolone acetate.
- H. As used herein, the term “USP” refers to United States Pharmacopeia, a nonprofit private group that develops standards of drug quality. “USP” followed by a chapter or section number refers to the indicated chapter or section of USP standards and/or tests.
- I. As used herein, the terms “NECC product” and “NECC products” refer to any compounded drug(s) that NECC or Ameridose provided to you for testing in 2012, including but not limited to compounded medications or pharmaceuticals.
- J. As used herein, “NECC cleanrooms” refers to the cleanrooms at the NECC facility.
- K. As used herein, the term “communication” includes, without limitation, every manner or means of statement, utterance, notation, disclaimer, transfer, or exchange of information of any nature whatsoever, by or to whomever, whether oral, written, or face-to-face, by telephone, U.S. mail or other delivery service, facsimile, personal delivery, electronic mail, computer, or otherwise, specifically including, without limitation, correspondence, conversations, dialogue, discussions, interviews, consultations, agreements, and other understandings.
- L. As used herein, the term “document” means any writing and other tangible thing in the custody, possession or control, or which was, but is no longer in the possession, custody, or control, of the answering party or known to the answering party—whether printed, recorded, reproduced by any process, or written or produced by hand, and whether or not claimed to be privileged or exempt from production for any reason—including, but not limited to, letters, reports, agreements, all official and personal communication, correspondence, telegraphs, memoranda, summaries, computer files or other electronic media, e-mails, records of personal conversations, formal or informal notes, diaries, forecasts, photographs, tape recordings, charts, plans, drawings, minutes or recordings of conferences, expressions or statements of policy, lists of persons attending meetings or conferences, summaries of interviews, reports and/or summaries of investigations, opinions or reports of records, and drafts of any documents, including original or preliminary drafts and subsequently revised versions. Any comment or notation appearing on any document, and not part of the original text, is to be considered a separate “document.” Requests for a “document” specifically includes electronic or magnetic data.
- M. As used in this document, the terms “identification,” “identify,” or “identity,” when used in reference:
  - a. to a person, means to state his or her full name and present or last known residential address and phone number;

- b. to a firm, company, business, trust, corporation, partnership, association, governmental agency, governmental unit, or other organization and/or entity, means to state its full name and present or last known business address and phone number;
  - c. to a statement and/or admission, means to identify who made it, who took or recorded it, and all others, if any, present during the making thereof; to state when, where and how it was taken or recorded, and to identify who has present possession custody or control thereof and/or who last had possession, custody, or control thereof;
  - d. to tangible things, recordings, photographs, videotapes, motion pictures, x-rays, and/or radiographic films means to give a reasonably detailed description thereof, including, if applicable, when, where, and how made; to identify who made it, and who has present possession, custody or control thereof, and/or who last had possession, custody or control thereof; and
  - e. to any documents, writings, and/or recordings means to set forth where the document exists, the date of authorship, the name of the author(s), a reasonably detailed description of its contents and all attachments to the original document, and the number of pages in the document and all attachments to the original document, and who has present possession, custody or control thereof, and/or who last had possession, custody or control thereof.
- N. As used herein, the terms “concerning,” “refer or relate,” or “referring or relating” mean, without limitation, referring to, relating to, having any relationship to, pertaining to, evidencing or constituting evidence of, originated by, representing, memorializing, summarizing, describing, discussing, analyzing, evaluating, directly or indirectly, or in whole or in part, the subject matter of the particular request.
- O. As used in herein, the term “person” includes any individual, natural person, partnership, association, organization, corporation, company, joint venture, firm, proprietorship, trust, estate, agency, board, authority, commission, or other legal or business entity of any kind.
- P. The singular includes the plural number, and vice versa. The masculine includes the feminine and neutral gender. The past tense includes the present tense where the clear meaning is not distorted by change of tense.
- Q. The term “any” should be construed to include the word “all,” and “all” should be construed to include “any.”
- R. The terms “and,” “or,” and “and/or” should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

**REQUESTS FOR ADMISSION**

**REQUEST FOR ADMISSION NO. 1:** Admit that you were hired by NECC to test NECC products, including but not limited to MPA.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 2:** Admit that you were hired by Ameridose to test NECC products, including but not limited to MPA.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 3:** Admit that you tested NECC products, including but not limited to MPA, in 2012.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 4:** Admit that you performed sterility testing on NECC products, including but not limited to MPA, in 2012.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 5:** Admit that you performed endotoxin testing on NECC products, including but not limited to MPA, in 2012.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 6:** Admit that you performed fungal testing on NECC products, including but not limited to MPA, in 2012.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 7:** Admit that you owed a duty to exercise reasonable care when testing NECC products.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 8:** Admit that you tested NECC products to determine whether such products were contaminated.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 9:** Admit that you did not discover contamination in any lots of MPA tested in 2012 from NECC or Ameridose.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 10:** Admit that Exhibit "A" is a true and correct copy of the page of your website located at [http://www.arlok.com/compounded\\_services.asp](http://www.arlok.com/compounded_services.asp) as of February 2015.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 11:** Admit that Exhibit "A" contains the same information that was on your website in 2012.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 12:** Admit that Exhibit "B" is a true and correct copy of the page of your website located at [http://www.arlok.com/microbiology\\_services\\_sterility.asp](http://www.arlok.com/microbiology_services_sterility.asp) as of February 2015.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 13:** Admit that Exhibit "B" contains the same information that was on your website in 2012.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 14:** Admit that Exhibit "C" is a true and correct copy of the page of your website located at [http://www.arlok.com/microbiology\\_services\\_fungal.asp](http://www.arlok.com/microbiology_services_fungal.asp) as of February 2015.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 15:** Admit that Exhibit "C" contains the same information that was on your website in 2012.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 16:** Admit that Exhibit "D" is a true and correct copy of the page of your website located at [http://www.arlok.com/microbiology\\_services\\_endotoxin.asp](http://www.arlok.com/microbiology_services_endotoxin.asp) as of February 2015.

**RESPONSE:**

**REQUEST FOR ADMISSION NO. 17:** Admit that Exhibit "D" contains the same information that was on your website in 2012.

**RESPONSE:**

#### INTERROGATORIES

**INTERROGATORY NO. 1:** Identify every person providing information used in answering these interrogatories.

**ANSWER:**

**INTERROGATORY NO. 2:** Identify by name and job title all of your officers, agents, employees, representatives, and contractors who provided any testing services on NECC products, including but not limited to MPA, in 2012.

**ANSWER:**

**INTERROGATORY NO. 3:** Identify each client for whom you provided testing services on MPA in 2011 and 2012.

**ANSWER:**

**INTERROGATORY NO. 4:** Identify and describe all testing services you performed on NECC products in 2012.

**ANSWER:**

**INTERROGATORY NO. 5:** Identify all policies, procedures, guidelines, standards and practices relating to sterility testing you performed on NECC products in 2012.

**ANSWER:**

**INTERROGATORY NO. 6:** Identify all policies, procedures, guidelines, standards and practices relating to fungal testing you performed on NECC products in 2012.

**ANSWER:**

**INTERROGATORY NO. 7:** Identify all policies, procedures, guidelines, standards and practices relating to endotoxin testing you performed on NECC products in 2012.

**ANSWER:**

**INTERROGATORY NO. 8:** Identify all policies, procedures, guidelines, standards and practices relating to potency testing you performed on NECC products in 2012.

**ANSWER:**

**INTERROGATORY NO. 9:** With respect to Exhibit "B" attached hereto, please describe all measures you took to comply with USP 71 when performing sterility testing on MPA from NECC or Ameridose in 2012.

**ANSWER:**

**INTERROGATORY NO. 10:** Describe all of your processes, procedures, and protocols related to ensuring that a customer provides the proper amount of sample material for sterility testing.

**ANSWER:**

**INTERROGATORY NO. 11:** Describe all measures you took to determine whether NECC or Ameridose submitted a sufficient amount of sample material for sterility testing of MPA in 2012.

**ANSWER:**

**INTERROGATORY NO. 12:** Describe all measures you took relating to testing MPA from NECC or Ameridose for fungal microorganisms in 2012.

**ANSWER:**

**INTERROGATORY NO. 13:** Describe all measures you took relating to endotoxin testing on MPA from NECC or Ameridose in 2012.

**ANSWER:**

**INTERROGATORY NO. 14:** Describe all investigations you undertook into any testing failures related to any NECC product.

**ANSWER:**

**INTERROGATORY NO. 15:** Identify and describe all audits on the testing services you provided to NECC or Ameridose to ensure the accuracy of such testing.

**ANSWER:**

**REQUESTS FOR PRODUCTION**

**REQUEST FOR PRODUCTION NO. 1:** The complete customer file you maintain for NECC.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 2:** The complete customer file you maintain for Ameridose.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 3:** All proposals, contracts and any other document containing or reflecting the terms and conditions pursuant to which you provided, or proposed providing, testing services for NECC and Ameridose.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 4:** All marketing materials you ever provided to NECC or Ameridose.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 5:** All correspondence between you and NECC referring or relating to any testing done on NECC products, including but not limited to MPA, in 2011 and 2012.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 6:** All correspondence between you and NECC referring or relating to testing methods or procedures you followed when testing NECC products, including but not limited to MPA, in 2012.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 7:** All correspondence between you and NECC referring or relating to the amount of sample material(s) provided to you by NECC or Ameridose in 2012.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 8:** All documents referring or relating to sterility testing of NECC products, including but not limited to MPA, in 2012.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 9:** All documents referring or relating to endotoxin testing of NECC products, including but not limited to MPA, in 2012.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 10:** All documents referring or relating to fungal testing on NECC products, including but not limited to MPA, in 2012.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 11:** All documents referring or relating to potency testing on NECC products, including but not limited to MPA, in 2012.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 12:** All policies, procedures, guidelines, and standards relating to the testing of any NECC product, including but not limited to MPA.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 13:** All documents referring or relating to audits or other measures you took to ensure the accuracy of testing services you provided to NECC or Ameridose.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 14:** All documents referring or relating to promises, representations, or warranties made to NECC or Ameridose.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 15:** All organizational charts for your company that applied during any year in which you performed testing services for NECC or Ameridose.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 16:** Every page of the <http://arlok.com/> website as it existed at any point in 2011 or 2012. If such documents are no longer available, produce documents reflecting the current content of your site.

**RESPONSE:**

**REQUEST FOR PRODUCTION NO. 17:** All documents and correspondence exchanged with any member of the PSC relating to NECC or Ameridose or the testing services provided to either.

**RESPONSE:**

Dated: March 9, 2015

By their attorneys,

/s/ Sarah P. Kelly  
Sarah P. Kelly (BBO #664267)  
skelly@nutter.com

NUTTER McCLENNEN & FISH LLP  
Seaport West  
155 Seaport Boulevard  
Boston, Massachusetts 02210  
(617) 439-2000  
(617) 310-9461 (FAX)

OF COUNSEL:

Yvonne K. Puig\*  
Texas State Bar No. 16385400  
yvonne.puig@nortonrosefulbright.com  
Adam T. Schramek\*  
Texas State Bar No. 24033045  
adam.schramek@nortonrosefulbright.com  
Eric J. Hoffman\*  
Texas State Bar No. 24074427  
eric.hoffman@nortonrosefulbright.com

NORTON ROSE FULBRIGHT US LLP  
98 San Jacinto Blvd., Suite 1100  
Austin, Texas 78701  
(512) 536-2450  
(512) 536-4598 (FAX)

Marcy Hogan Greer\*  
Texas State Bar No. 08417650  
mgreer@adjtlaw.com

ALEXANDER DUBOSE JEFFERSON &  
TOWNSEND LLP  
515 Congress, Suite 2350  
Austin, Texas 78701  
(512) 482-9300  
(512) 482-9303

\*Appearing Pro Hac Vice

**CERTIFICATE OF SERVICE**

I certify that the foregoing document was served in the following manner on the 9th day of March, 2015.

Kenneth B. Walton  
Kristen R. Ragosta  
Donovan Hatem, LLP  
53 State Street, Eighth Floor  
Boston, MA 02109  
[kwalton@donovanhatem.com](mailto:kwalton@donovanhatem.com)  
[kragosta@donovanhatem.com](mailto:kragosta@donovanhatem.com)

J. Gerard Stranch, IV  
Benjamin A. Gastel  
Branstetter, Stranch & Jennings PLLC  
227 Second Avenue North  
Nashville, TN 37201  
[gerards@bsjfirm.com](mailto:gerards@bsjfirm.com)  
[beng@bsjfirm.com](mailto:beng@bsjfirm.com)

*Via U.S. Mail and Electronic Mail*

*Via Electronic Mail*

C.J. Gideon  
Chris Tardio  
Gideon, Cooper & Essary PLC  
315 Deaderick St., Suite 1100  
Nashville, TN 37238  
[cj@gideonecooper.com](mailto:cj@gideonecooper.com)  
[chris@gideonecooper.com](mailto:chris@gideonecooper.com)

James Rehnquist  
Roberto M. Braceras  
Goodwin Procter, LLP  
Exchange Place  
53 State Street  
Boston, MA 02109  
[jrehnquist@goodwinprocter.com](mailto:jrehnquist@goodwinprocter.com)  
[rbraceras@goodwinprocter.com](mailto:rbraceras@goodwinprocter.com)

*Via Electronic Mail*

*Via Electronic Mail*

O. Mark Zamora  
Mark Zamora & Associates  
P.O. Box 660216  
Atlanta, GA 30366  
[mark@markzamora.com](mailto:mark@markzamora.com)

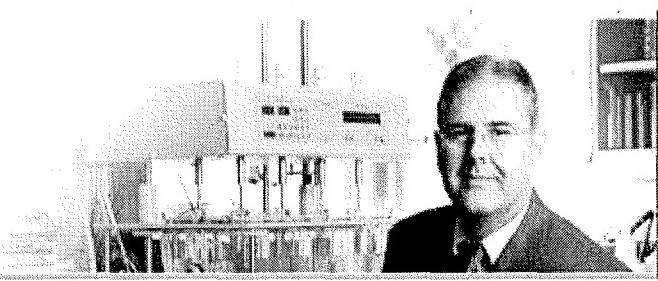
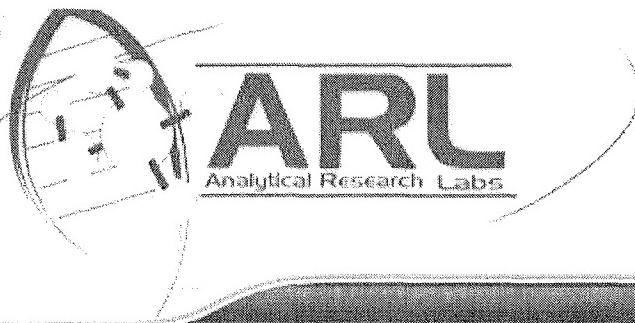
Frederic L. Ellis  
Ellis & Rapacki  
85 Merrimac Street  
Suite 500  
Boston, MA 02114  
[rellis@ellisrapacki.com](mailto:rellis@ellisrapacki.com)

*Via Electronic Mail*

*Via Electronic Mail*

/s/ Sarah P. Kelly  
Sarah P. Kelly

# Exhibit A

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Analytical Research Laboratories  
840 Research Parkway, Ste. 546  
Oklahoma City, OK 73104  
Toll Free: (800) 393-1595  
Phone: (405) 271-1144  
Fax: (405) 271-1174  
E-mail: [info@arlok.com](mailto:info@arlok.com)

ARL strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting. We offer a full range of laboratory services, both analytical and microbiological. Click on one of the services below to find out how we may enhance your quality program.

**Services Offered:**

- Potency Determination
- Sterility
- Endotoxin
- Fungal
- Bacterial ID
- Stability Studies
- Content Uniformity
- Particulate Matter
- Dissolution/Disintegration
- Drug Diversion/Complaint Sample Testing
- Unknown Determination
- Deformulation
- Formulation Development
- Electrolyte Testing



The list above only represents a portion of the services that we offer. In addition to the services mentioned above, ARL has a full service laboratory that can provide analytical and microbiological services to meet just about any need.

[ARL Pharmacy Brochure](#)[ARL Technical Brochure](#)[ARL Marketing Brochure](#)

For more information on pharmacy services contact:

Pharmacy Sales, Susan Adams - [sadams@arlok.com](mailto:sadams@arlok.com)  
Technical Sales, Brian Kelley - [bkelley@arlok.com](mailto:bkelley@arlok.com)  
Technical Sales, Kathy Heatherly - [kheatherly@arlok.com](mailto:kheatherly@arlok.com)

or call (800) 393-1595

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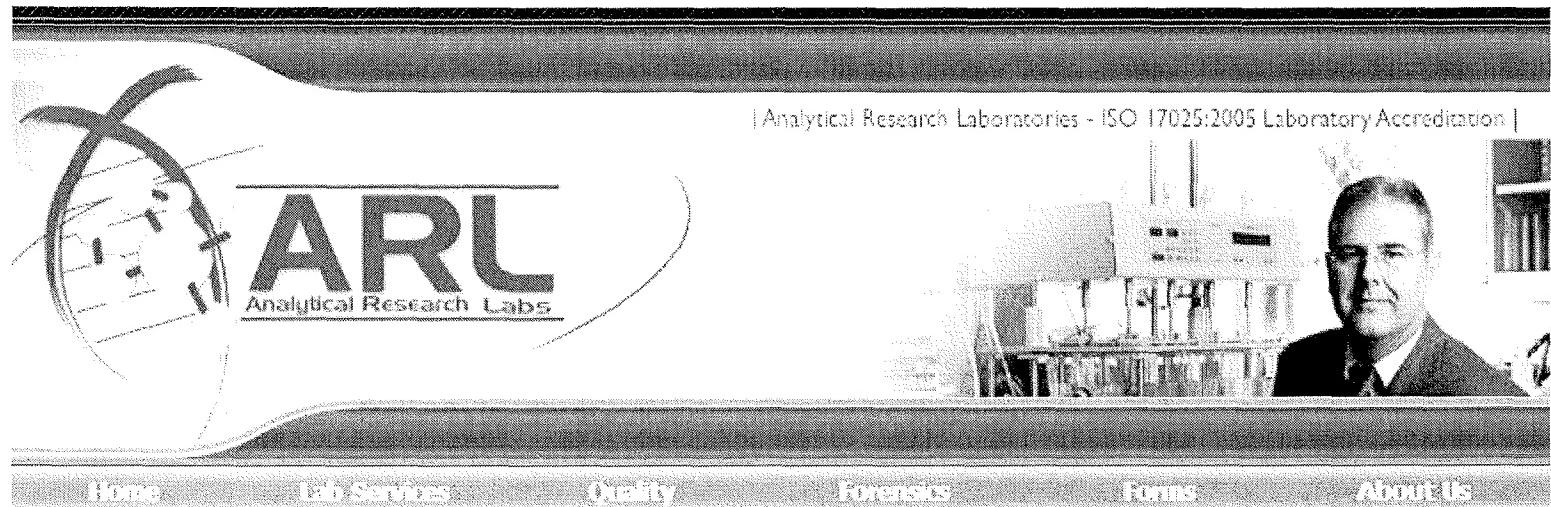
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ISO 17025:2005 Laboratory Accreditation

ARL is accredited to the ISO 17025:2005 standard as applicable to our scope of accreditation

# Exhibit B



| Analytical Research Laboratories - ISO 17025:2005 Laboratory Accreditation |

## Request A Quote

## How To Choose a Contract Lab

## How To Submit A Sample

## Quality

### To Contact Us:

Analytical Research Laboratories  
840 Research Parkway, Ste. 546  
Oklahoma City, OK 73104  
Toll Free: (800) 393-1595  
Phone: (405) 271-1144  
Fax: (405) 271-1174  
E-mail: [info@arlok.com](mailto:info@arlok.com)

## Microbiological Services | Testing Services | Sterility

ISO 17025:2005 Accredited for Microbiology, Testing Services, and Sterility.

**Sterility testing USP <71>** - In order to cite USP <71> as the test method, you must submit a copy of a formulation sheet and sufficient sample material to perform method suitability testing the next time you submit a product for sterility testing. In addition, you must verify each time that you submit articles for sterility testing that the number of articles submitted is consistent with the requirements of Chapter <71> of the U.S. Pharmacopoeia. Details follow.

A formulation sheet with a unique identifying number (that you generate) must be submitted for each unique preparation. ARL will be able to definitively show that method suitability data is traceable to the earlier unique formulation if the previously submitted formula identification number is provided. Failure to provide a number for the formulation will result in a requirement for additional sample(s) to be provided for method suitability testing, and your facility may experience delays in reporting of results. The first time sterility testing is performed on that particular formulation, you need to send approximately 6 times your normal sample amount (not to exceed 200mL). Please identify on the submission form what articles are for method suitability testing and which articles are for testing. Additionally, if you confirm that the number of articles submitted for testing is in compliance with USP <71>, the report on those articles will cite USP <71>. Please reference USP <71> for the correct number of articles to submit for testing. Remember to submit an additional sample if you have also requested fungal or chemical testing.

**Sterility testing MBI-144** - This is an internal ARL method that will be cited in the event that you do not provide the proper number of articles per USP <71> or method suitability cannot be traced to your specific formulation. This method does not comply with USP <71>.

Sterility testing is performed in a certified, environmentally controlled suite that is managed in accordance with current aseptic processing guidelines.

Negative controls are used daily and positive controls are used during the initial testing of samples when method suitability testing is performed.

We examine each sterility test for growth at intervals during the incubation and at its conclusion. If a test shows no evidence of microbial growth in either media over the incubation period, then it complies with the test for sterility.

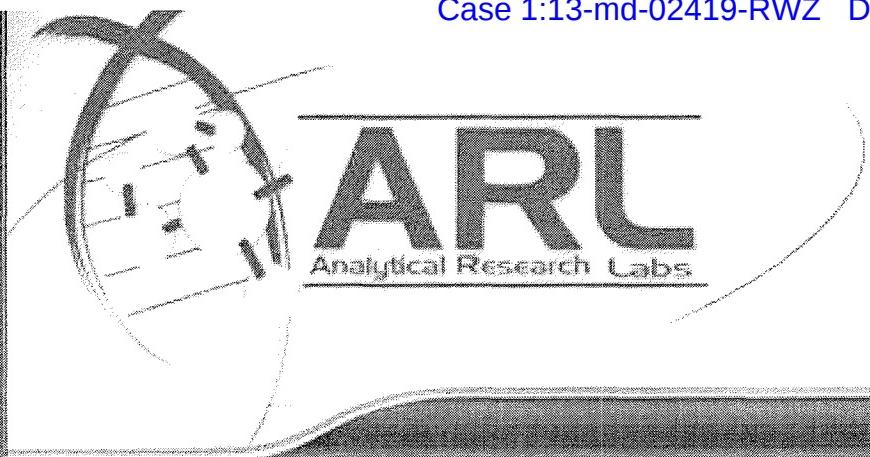
A preliminary sterility report is available after 72 hours of incubation.

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### ISO 17025:2005 Laboratory Accreditation

ARL is accredited to the ISO 17025:2005 standard as applicable to our scope of accreditation that outlines general requirements for the competence of testing and calibration laboratories.

# Exhibit C



## Laboratory Services, Research & Development

### Forensic and Analytical Expertise

"Quality service through experience and excellence . . ."

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#### To Contact Us:

Analytical Research Laboratories  
840 Research Parkway, Ste. 546  
Oklahoma City, OK 73104  
Toll Free: (800) 393-1595  
Phone: (405) 271-1144  
Fax: (405) 271-1174  
E-mail: [info@arlوك.com](mailto:info@arlوك.com)

[Microbiological Services](#) | [Testing Services](#) | [Fungal](#)

Quality service through experience and excellence . . .

Analytical Research Labs has developed an alternative method specifically designed for examining products required to be sterile for fungal microorganisms. ARL utilizes selective media specifically designed for the growth of fungal contamination. Its selective properties, lower pH and high dextrose concentration, target the recovery of fungal contaminants by inhibiting the growth of bacteria. Like the sterility test, the test preparations are observed for macroscopic evidence of microbial growth and at the end of the incubation period (14 or 18 days) a final result is released.

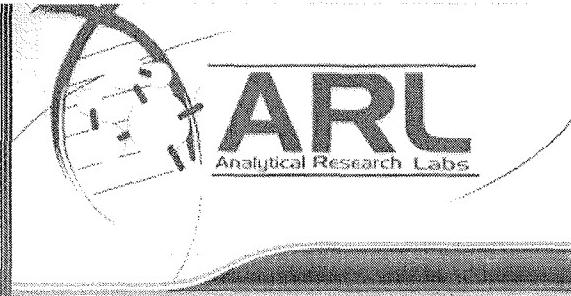
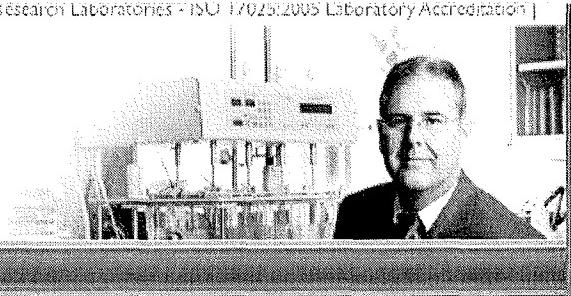
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#### ISO 17025:2005 Laboratory Accreditation

ARL is accredited to the ISO 17025:2005 standard as applicable to our scope of accreditation that outlines general requirements for the competence of testing and calibration laboratories.

# Exhibit D

[Analytical Research Laboratories • ISO 17025:2005 Laboratory Accreditation]

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**To Contact Us:**  
 Analytical Research Laboratories  
 840 Research Parkway, Ste. S46  
 Oklahoma City, OK 73104  
 Toll Free: (800) 393-1595  
 Phone: (405) 271-1144  
 Fax: (405) 271-1174  
 E-mail: [info@arlok.com](mailto:info@arlok.com)

[Microbiological Services](#) | [Testing Services](#) | [Endotoxin](#)

**Endotoxin testing USP <85>** - To calculate an Endotoxin limit, you must provide ARL with the maximum dosage per hour, average patient weight and route of administration. For veterinary use, the client must also include the largest dose in the smallest animal.

This information is needed in order to establish the most accurate endotoxin limit for your product as is outlined in USP <85>.

**Endotoxin testing MBI-145** - This is an internal ARL method that will be cited in the event that you do not provide maximum dosage per hour, average patient weight and route of administration. This method does not comply with USP <85>.

**What are endotoxins?**  
 Endotoxins are a toxic substance found in the cell wall of gram negative bacteria and are released after death and lysis of the cell. The release of endotoxin in the body can cause a range of symptoms, such as fever, hypertension, shock, and disseminated intravascular coagulation.

The Limulus Amebocyte Lysate (LAL) test is an invitro assay for detection and quantitation of bacterial endotoxins.

**Routine Analysis**  
 Endotoxin analysis should be accurate and objective. Why be unsure if the gel formed, when you can know for sure what is there? With each test run we perform a system suitability on your product which tells us if there is interference or true endotoxin present. No matter the product; oils, suspensions, radiopharmaceuticals - we have a method that can work for you. We can help you calculate the endotoxin limit on all your drugs or do it for you. Let us help you confidently deliver a safe and reliable product to the ones you serve.

**Method Development and Validation**  
 We offer a variety of services for your endotoxin needs. Whether its method development for a new product line or routine endotoxin testing, we can help.

Validated test methods require that we test three different lots to pass the following criteria:  
 Absolute value of the R-value > 0.98  
 Negative Water Controls (NWC) > lambda onset times  
 CV's between standards and Positive Product Controls < 10%  
 CV's between unknowns < 20%  
 Spike Recovery for each lot of product must be between 50% and 200%  
 pH of Sample + LAL between 6 and 8

Endotoxin testing is necessary for:  
 Injectables or parenteral products  
 Radiopharmaceuticals and cytotoxic agents  
 Water for injection (WFI)  
 Validation of depyrogenation processes

Source of endotoxin contamination:  
 Water  
 Raw compounds  
 Instruments  
 Method of storage between preparation and sterilization  
 Inadequate depyrogenation cycle

Inadequate depyrogenation cycles

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Contact Us By Phone: (800) 393-1595